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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/945,425	10/21/1997	CHRISTER CEDERBERG	1103326-282	2696

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WHITE & CASE LLP
PATENT DEPARTMENT
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[REDACTED] EXAMINER

DESAI, RITA J

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 04/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	08/945,425	CEDERBERG ET AL.
	Examiner	Art Unit
	RITA J. DESAI	1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 March 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-11, 18, 19, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-11, 18, 19, 26 and 27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>24</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Request for Continued Examination Application

The request filed on 3/8/2002, for a Request of Continued Examination, Application (RCE) under 37 CFR 1.114 based on parent Application No. 08/945,425 is acceptable and a RCE has been established. An action on the RCE follows.

Response to Arguments

The CPA filed 1/9/2001 under 35 USC 1.53d based on application # 08/945,425 filed 10/21/1997 has been acknowledged. Thus the rejection of claims 1-11,15,16,18-21, 23-25 under 35 USC 102 e has been withdrawn since 35 USC 103c now applies based on MPEP 706.02(l)(1) column 2 lines 4-9, page 700-36.

The rejection of claims 1-11,15,16,18-21, 23-25 under 35 USC 103 over 982 still stands since even though the reference teaches a combination it clearly teaches the extended release of the drugs which would increase the concentration of the drug in the blood plasma. Also Helicobacter pylori infection may increase or decrease acid secretion and may augment or decrease the proton pump inhibitor efficacy and treatment of Z-E syndrome is caused by gastric acid hypersecretion in patients hence the combination of an antimicrobial active ingredient is obvious and does not diminish the use of a proton pump inhibitor in a slow release form.

NEW GROUNDS of REJECTION

Applicant's arguments with respect to claim 1-11,15,16,18-21, 23-25 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11,15,16,18-21, 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/01624 Bergstrand et al. Publication date Jan 25 1996. (as per the filing date of PCT application , or 102 e based on the foreign priority)

The claims discloses dosages of the compounds similar to those of the invention used as acid labile H⁺K⁺-ATPase inhibitor. In the background of the invention lines 16-18 the compounds of the invention are disclosed as being gastric proton pump inhibitors. The same compounds as those of the invention are disclosed.

The recitation of "inducing an extended blood plasma profile "has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11,15,16,18-21, 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Martindale The extra pharmacopoeia 1993, page 897 middle column.

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The reference clearly discloses that doses should be divided into more than once , to be more effective, for Zollinger –Ellison syndrome. (gastric acid secretion) See page 896, under Omeprazole to page 897 middle column.

Also see Gray US 5888535 which teaches Pantoprazole as an inhibitor of H⁺ release and is therefore useful in the treatment of other conditions related to gastric hypersecretion such as Z-E Syndrome.

Conclusion

The rejections on the claims 1-11,18,19,26 and 27 still stand.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RITA J. DESAI whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday,9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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R.D.

April 2, 2002



ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600